REMARKS

The present application includes claims 1-21. Claims 1-21 have been rejected. By this Response, claims 10-11 and 21 have been canceled, and claims 1, 8, and 14 have been amended.

Claim Amendments

Claim 1 has been amended to recite that the tracking system compares measurements from the instrument with a model for the instrument to determine a variation based on deformity of the instrument. Additionally, the tracking system adjusts tracking of the instrument based on the variation.

Claim 8 has been amended to recite comparing the model of the instrument with a mathematical model of the instrument to determine a variation based on deformity of the instrument and adjusting tracking of the instrument based on the variation.

Claim 14 has been amended to recite comparing the representation of the instrument and a computer-generated model of the instrument to identify variation between the representation and the model based on deformity of the instrument. Amended claim 14 recites adjusting the representation of the instrument based on the variation and facilitating performance of an image-guided operation using an image data set and representation of the instrument.

The Applicant submits that amended claims 1, 8, 14, and their dependent claims should be allowable over the cited art of record.

Rejections under 35 U.S.C. §102

Claim 1-4 and 6-11 were rejected under 35 U.S.C. 102(b) as being anticipated by DiGioia III et al. (U. S. Patent No. 5,880,976).

However, DiGioia relates to determining an artificial joint implant position based on component models used to simulate movement in the patient's joint with the artificial component in a test position. See, e.g., Abstract. Implant position in the patient's joint based on a predetermined range of motion and calculated range of motion. See, e.g., Abstract. The system of DiGioia uses a pre-operative geometric planner, a pre-operative biomechanical simulator and navigation software to guide a medical practitioner in the placement of implant components at implant positions. See, e.g., col. 6, ll. 10-44. A skeletal model is created to help in determining joint motion for implant placement in a patent. See, e.g., Fig. 2 and associated description. Furthermore, rather than identifying features and/or fiducials, DiGioia relies on light-emitting diodes (LEDs) for tracking in an optical tracking system. See, e.g., col. 6, ll. 45-67. DiGioia simply uses a coordinate transformation to align the joint model with the intra-operative position of the patient's joint. See, e.g., col. 8, ll. 33-59. Based on a patient skeletal model and observations regarding range of motion, placement of an implant is determined.

DiGioia measures movement of a human joint, rather than identifying and accounting for a deformity in an instrument, as recited in claims 1 and 8 and their dependent claims. In fact, DiGioia does not relate to measuring or modeling ***instruments*** at all. Additionally, DiGioia does not measure fiducials on an instrument (or an anatomy), let alone a plurality of fiducials, as recited in claims 1 and 8 and their dependents. In the present claims, measurements of a plurality of fiducials help identify and account for deformity in the instrument being measured, for example. Furthermore, DiGioia does not compare measurements or a measured model of an instrument with a mathematical or other model of the instrument to determine a variation based on deformity of the instrument and then adjust tracking of the instrument based on the variation, as recited in claims 1 and 8 and their dependent claims.

In addition, DiGioia does not place and/or measure a plurality of indentation and/or or groove fiducials on an instrument, as recited in claim 2. DiGioia fails to disclose a measurement frame, as recited in 7, but rather discusses an acetabular cup 70 implant.

Thus, for at least these reasons, the Applicant submits that claims 1-4 and 6-11 should be allowable over the cited art.

Claims 14, 16-18, and 20 were rejected under 35 U.S.C. 102(e) as being anticipated by Grimm et al. (U.S. Patent App. Pub. No. 2004/0153191).

However, Grimm relates to registering an orthopedic implant in a computer assisted navigation system. See, e.g., Abstract and para. [0002]. Grimm uses a registration device that must be detachably secured to the implant in order to perform position calibration. See, e.g., para. [0006]. The registration device must be engaged with an implant in a predefined relative position. See, e.g., para. [0006]. The registration device includes slots to place an implant in the slots for registration. See, e.g., para. [0025]. Grimm for an anatomical structure model from images of that structure. See, e.g., para. [0046]. Grimm simply registers an image coordinate system with an anatomical coordinate system and displays relative position and orientation of the implant with respect to the anatomical structure using previously acquired three-dimensional models of the anatomy. See, e.g., para. [0050]-[0051].

Grimm discloses none of the steps recited in the method of claim 14 and its dependent claims 16-18 and 20. For example, Grimm does not disclose obtaining a plurality of measurements for said instrument using a plurality of fiducials on an instrument. Grimm does not teach or suggest determining a representation of the instrument in a reference coordinate system using the plurality of measurements for use in tracking the instrument. Additionally,

Grimm fails to disclose comparing the representation of the instrument and a computer-generated model of the instrument to identify variation between the representation and said the based on deformity of the instrument. Furthermore, Grimm fails to disclose adjusting the representation of the instrument based on the variation and facilitating performance of an image-guided operation using an image data set and representation of the instrument.

Thus, for at least these reasons, the Applicant submits that claims 14, 16-18, and 20 should be allowable over the cited art.

Rejections under 35 U.S.C. §103

Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia.

As discussed above, DiGioia fails to teach or suggest the elements recited in independent claim 1, from which claim 5 depends. Furthermore, as noted by the Examiner, DiGioia fails to disclose determining a closed form registration for the instrument. DiGioia fails to disclose using closed form registration to calibrate the instrument, as recited in claim 5. As discussed in exemplary embodiments in the specification of the present application, certain embodiments use closed form registration to calibrate deformed instruments in a surgical navigation system. Using closed form registration of an instrument, a solution is overdetermined using multiple data points. That is, the geometry of an instrument may be described specifically. A computer-aided design (CAD) model of the instrument is created. Several fixed points on the instrument are sampled. A mathematical model of where the sampled points should theoretically be located is generated using the CAD model. Using the sampled coordinates and the ideal coordinates, a solution for the position of the sampled points in a reference coordinate frame is determined. Such a registration technique was not envisioned in DiGioia and provides advantages for at least

the system to which it is applied in claim 5 of the present application. The Applicant respectfully submits that one of ordinary skill in the art would not have applied closed form registration as claimed in claim 5, and, therefore, its results would not have been expected. The Applicant respectfully submits that the system of claim 5 represents a patentable improvement and, for at least these reasons, should be allowable over the cited art of record.

Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia in view of Krause et al. (U.S. Patent No. 6,701,174).

As discussed above, DiGioia fails to teach or suggest the limitations of independent claim 8, from which claim 13 depends. DiGioia fails to disclose accommodating deformity of an instrument, let along updating a model of an internal object after a deformation, as asserted by the Examiner. Rather, DiGioia makes observations to derive a range of movement of a patient skeletal structure, such as a joint, to aid in placement of an implant. See, e.g., col. 10, ln. 54 – col. 11, ln. 9.

Additionally, Krause '174 relates to computer-assisted orthopedic surgery planner software for generation of 3D solid bone models from 2D X-ray images of a patient's bone. See, e.g., Abstract and col. 1, ll. 15-20. Krause '174 involves no tracking and is used for remote training and pre-surgery guidance to a surgeon, rather than to calibration of an instrument as recited in claim 13. See, e.g., Abstract and col. 3, ll. 9-11. Additionally, in Krause '174, rather than adjusting tracking based on variation between a computer-generated or mathematical model and a measured physical model, as recited in independent claim 8, Krause '174 adjusts a 3D template based on 2D patient images. See, e.g., col. 5, ll. 13-25. Note that Krause '174 uses the word "deform" to indicate an adjustment or modification of a 3D template model based on

observed data. The template model of Krause '174 is a very general geometric model that is refined based on bone contours identified through processing of 2D images of the particular bone. See, e.g., col. 12, ll. 4-62. As defined in Krause '174, "[d]eformations allow the user to treat a solid as if it were constructed from a special type of topological putty or clay which may be bent, twisted, tapered, compressed, expanded, and otherwise transformed repeatedly into a final shape." Col. 12, ln. 66 – col. 13, ln. 24. Thus, Krause '174 clearly intends a different use of deformation on a general, geometric, volume-based putty model rather than obtaining a plurality of measurements for an instrument after the instrument has been deformed. Again, Krause '174 does not measure an instrument and does not accommodate deformations of the instrument as described, for example, in the present application.

Thus, for at least these reasons, the Applicant submits that claim 13 should be allowable over the cited art.

Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm.

As discussed above, Grimm fails to teach or suggest the limitations of independent claim 14, from which claim 15 depends. Additionally, as echoed by the Examiner, Grimm fails to disclose closed form registration, let alone determining a closed form registration for an instrument using a plurality of measurements. As discussed above with respect to claim 5, use of closed form registration was not an obvious design choice and provides benefits in the claimed instrument registration process not found in the art of record. As discussed in exemplary embodiments in the specification of the present application, certain embodiments use closed form registration to calibrate deformed instruments in a surgical navigation system. Using closed form registration of an instrument, a solution is overdetermined using multiple data

points. That is, the geometry of an instrument may be described specifically. A computer-aided design (CAD) model of the instrument is created. Several fixed points on the instrument are sampled. A mathematical model of where the sampled points should theoretically be located is generated using the CAD model. Using the sampled coordinates and the ideal coordinates, a solution for the position of the sampled points in a reference coordinate frame is determined. Such a registration technique was not envisioned in Grimm and provides advantages for at least the method to which it is applied in claim 15 of the present application. The Applicant respectfully submits that one of ordinary skill in the art would not have applied closed form registration as claimed in claim 15, and, therefore, its results would not have been expected. The Applicant respectfully submits that the system of claim 15 represents a patentable improvement and, for at least these reasons, should be allowable over the cited art of record.

Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm in view of Krause et al. (U.S. Patent No. 6,711,432). As discussed above, Grimm patent fails in many respects to teach the limitations of independent claim 14, let alone its dependent claim 21, which has now been incorporated into independent claim 14. Additionally, the Krause '432 patent uses software to generate a three-dimensional model of an area of a patient upon which a surgical procedure is to be performed using a template database but fails to provide any teaching or suggestion of using that template in comparison to a current, generated model of an instrument to determine a variation. See, e.g., Abstract; col. 1, ll. 11-31; col. 4, ll. 33-42. Rather, Krause '432 compares templates of misaligned bones and properly aligned bones for a surgeon's visual review. Col. 4, ll. 33-42. Therefore, for at least these reasons, the Applicant submits that Krause

'432 fails to cure the deficiencies of Grimm, and the combination fails to teach or reasonably suggest the limitations of claim 14 (or previously-pending claim 21).

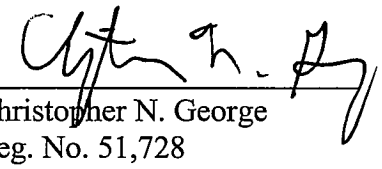
CONCLUSION

The Applicants submit that the present application is in condition for allowance. If the Examiner has any questions or the Applicants can be of any assistance, the Examiner is invited and encouraged to contact the Applicants at the number below.

The Commissioner is authorized to charge any additional fees or credit overpayment to the Deposit Account of GTC, Account No. 070845.

Respectfully submitted,

Date: July 10, 2007



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